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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/522,540

08/22/2005

Peter Forsell

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EXAMINER

PRONE, CHRISTOPHER D

ART UNIT

PAPER NUMBER

3738

MAIL DATE

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05/21/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/522,540	<b>Applicant(s)</b> FORSELL, PETER	
	<b>Examiner</b> CHRISTOPHER D. PRONE	<b>Art Unit</b> 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 19,24-26,29 and 31-71 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19,24-26,29 and 31-71 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Objections***

Claims 20, 21, 35, 36, 42, 54, 64, and 68, are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. All of the subject matter of claim 20 is currently contained within claim 19 from which it depends. The other claims are all contained within the independent claims from which they depend.

### ***.Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 37 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim has been amended to require that the second layer covers said base material tubing "without and within". The examiner does not understand what the applicant means by "without and within". The phrase within and without is not appropriate for this context.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 38, 39, 66, and 67 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims require that the property improving means comprises a gas but depends from claims that require the filler material to be a viscoelastic material. Every time the specification refers to viscoelastic materials it goes back to silicones. There is no mention of gases that are viscoelastic and one of ordinary skill within the art would not conclude to use gases for constructing the current invention when reading that the property improving means is viscoelastic. Furthermore in regards to claims 66 and 67 one would not be inclined to make the polyurethane into a gas from reading the current application.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40, 55, 59, 61, and 68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 40 states that the base material comprises PTFE but it depends from claim 38 which depends from claim 19

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that states that the base material comprises silicone. Claim 68 is similar but changes the base material from polyurethane in claim 51 to PTFE. Claims 55, 59, and 61 state that the viscoelastic material comprises silicone gel, cellulose gel, or collagen gel, but depend from claim 51 that states that the viscoelastic material comprises silicone polyurethane. The applicant is required to amend the claims to define what he intends the base material and viscoelastic material to comprise.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19, 24-26, 29, 31-39, 41, and 42-71 are rejected under 35 U.S.C. 103 as being unpatentable over Kuyava WO 01/67996 A2.

Kuyava discloses the invention substantially as claimed being an implant for use inside a human body comprising a tubular inflatable base with curved interior surfaces made of silicone coated in poly-para-eylylene or Parylene having a core filled with viscoelastic fluid. Kuyava further teaches the use of inflatable double walled cylinders with coatings on each layer. However, Kuyava does not disclose the fluid filler materials.

Kuyava teaches that the features of penile prosthesis could be applied to breast implants (3:46-54). It is old and well known within the art of breast implants to use silicone gel as viscoelastic filler material.

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It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the silicone gel as the filler fluid with the penile implant in order to enhance the viscoelastic properties of the device.

In regards to claim 34 Kuyava does not disclose the use of a second layer comprising polyurethane. In paragraph [0012] of the current application the applicant discloses that Elastic comprises is a commercially available material that comprises polyurethane and is used to coat implants. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the Elastic coating with the implant of Kuyava in order to enhance cell-barrier protection of the implant.

In regards to claim 34 Kuyava does not disclose the use of a second layer comprising polyurethane. In paragraph [0012] of the current application the applicant discloses that Elastic comprises is a commercially available material that comprises polyurethane and is used to coat implants. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the Elastic coating with the implant of Kuyava in order to enhance cell-barrier protection of the implant.

In regards to claims 38 and 39 Kuyava does not disclose the use of a gas for filler material. It is old and well known that fluids, gases, and gels are interchangeable for use in filling implants. Ledergerber USPN 4,955,907 is a reference supporting that implants can use a variety of the filling materials such as fluids, gels, and gases.

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. It would have been obvious to one having ordinary skill in the art at the time the invention was made to try gas to fill the implant of Kuyava in place of the fluid because they are known equivalents.

Claim 40 is rejected under 35 U.S.C. 103 as being unpatentable over Kuyava WO 01/67996 A2 in view of Timm et al. USPN 4,517,967.

Kuyava discloses the invention substantially as claimed being described supra. However, Kuyava does not disclose that the base member is made from PTFE

Tim teaches the use of PTFE for penile implants is old and well known in the same field of endeavor for the purpose of providing a flexible resilient implant.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the PTFE base material with the implant of Kuyava in order to provide a flexible resilient implant.

### ***Response to Arguments***

Applicant's arguments filed 2/25/09 have been fully considered but they are not persuasive. The applicant argues that the Kuyava reference does not anticipate the claims because it does not recite all the claim requirements including the property improving means, but the rejection already addressed this in referring to Kuyavas disclosure of a viscoelastic fluid as the property improving means. The applicant then argues that commercially available or well known in the art do not make things obvious

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and that concrete factual evidence is required to support a rejection. The concrete factual evidence is the admittance by the applicant that they are commercially available and commonly used.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER D. PRONE whose telephone number is (571)272-6085. The examiner can normally be reached on Monday through Fri 8:30 to 5:00.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher D Prone  
Examiner  
Art Unit 3738

/Christopher D Prone/

/Corrine M McDermott/  
Supervisory Patent Examiner, Art Unit 3738